

### **REMARKS**

Claims 56, 57, 61-65, 70-76, and 78-81 are pending in the application. Claims 56, 71 and 78 have been amended to include the further limitation that the composition be abrasive free. This amendment is supported by the specification at paragraph 18 and the sample formulations listed in Tables 1-3. No new material has been added.

Reconsideration and favorable action are respectfully requested. Applicant respectfully traverses the rejection.

#### **Claims 56-58, 61-63, 64, 67-73-76 and 78-81 rejected under 35 U.S.C. § 103(a)**

Claims 10-12 and 20-25 are rejected under 35 U.S.C. § 103. The following is a quote of 35 U.S.C. § 103(a) upon which the Examiner bases the rejections:

“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

#### **Claims 56-58, 61, 63, 64, 67-73, 76, 78, 80 and 81 under 35 U.S.C. § 103 over Williams in view of Collin**

Claims 56-58, 61, 63, 64, 67-73, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Collin et al. (US 5,033,650).

Williams et al. disclose two part oral compositions wherein one part comprises peroxide or a peroxide releasing component and the second part comprises bicarbonate. The compositions are formulated into gels and pastes and may be kept isolated in a separate compartment of a dispenser such as those disclosed by Schaeffer (US 4,849,213), which shows a dispenser comprising a compartment where the two components mix before being dispensed from the dispenser (Fig. 1 of Schaeffer). The mixture of the two components will provide a composition with a pH ranging from 7.0 to 9.5 (col. 4, lines 3-9). The peroxide releasing component includes an alkali metal percarbonate. The compositions may also comprise tartar control agents such as

disodium pyrophosphate (col. 4, lines 47-58). Humectants include polyethylene glycol and may comprise 25 to 90% by weight and water may comprise 3 to 30% by weight. The reference differs from the instant claims insofar as it does not disclose the dispensers comprise a static mixer.

Collin et al disclose a multiple barrel dispensing device for intermixing at least two viscous materials and for dispensing the mixed product in a preferred volumetric ratio. The device comprises a syringe having a plurality of elongated storage compartments for independently storing the material to be intermixed and a common head having a separate channel extending from each compartment for discharging stored materials from a common discharge end of said head (col. 2, lines 8-10). It further comprises a nozzle having a common static mixing element.

Applicant respectfully traverses the rejection.

Williams teaches away from the present invention. Applicant has amended claims 6, 71 and 78 have been amended to include the further limitation that the composition be abrasive free.

Williams teaches a two-component toothpaste which contains an abrasive. (Col. 4, lines 38-47). According to the present invention tooth whitening toothpaste are “mechanically agitated at the stained tooth surface in order to affect tooth stain removal through abrasive erosion of stained acquired pellicle.” (Paragraph 5)

On the other hand, the present invention teaches a composition that accomplishes “the tooth-bleaching effect by a chemical process....” (Paragraph 5). As such, the present invention has no need for the inclusion of an abrasive since mechanical agitation is not involved. Therefore, Williams teaches away from the present invention.

According to the Examiner, Williams and the present invention have a slight overlap with respect to the concentration of peroxide in the composition and that such an overlap is a prima facie case of obviousness. However, according to the Manual of Patent Examining Procedure § 2144.05(III), the Applicant can rebut this prima facie case of obviousness if it can be shown that the prior art teaches away from the present invention.

Williams teaches away from the present invention regarding the hydrogen peroxide concentration. In Williams, the hydrogen peroxide content that is disclosed is for anti-microbial effect. The article and patents cited in Williams all disclose oral compositions where peroxide is added for anti-microbial effect. (Col. 1, lines 11-66).

Williams teaches peroxide mainly in the lower range because high concentrations of peroxide are harmful to the soft tissue of the oral cavity. Since Williams discloses a toothpaste, the composition will come into contact with the soft tissue of the oral cavity when users are brushing their teeth. As such, Williams teaches the use of a lower concentration of peroxide to prevent patient discomfort. Further supporting the fact that Williams teaches low concentrations of hydrogen peroxide is that Williams discloses that "In terms of active weight hydrogen peroxide, the amount will range from about 0.5% to about 3%, preferable from about 0.8% to about 1.8%, optimally between about 1% and 1.5% by weight of the gel component." (Col. 3, lines 27-31).

Additionally, the concentration of peroxide that is in Williams is too low for a detectable tooth whitening effect under the conditions in which Williams is used. Williams discloses a range of peroxide between 0.1 to about 10%. The present invention has a range of peroxide above 10% and there is a slight overlap at the 10% mark.

On the other hand, the present invention teaches a higher concentration of peroxide because it will only be applied to the teeth. Unlike brushing teeth where the composition will come into contact with the soft tissue of the oral cavity as a result of the mechanical agitation of the composition by the toothbrush, during a tooth whitening procedure, the composition will not come into contact with the soft tissue of the oral cavity. As a result, higher concentrations of peroxide can be used since soft tissue irritation is no longer an issue and higher concentration of hydrogen peroxide is one factor in many for teeth whitening. As a result, Williams teaches away from the present invention.

The Examiner believes that the concentration of hydrogen peroxide is a result effective variable. As a result, Examiner believes that optimization of the hydrogen peroxide concentration is optimization of a result effective variable which is obvious.

Applicant respectfully points out that concentration of hydrogen peroxide is just one element of the tooth whitening reaction. There are so many other variables involved in the reaction. Table 4 is a good example of how the tooth whitening reaction is not just limited to hydrogen peroxide. Table 4 illustrates that aside from hydrogen peroxide content, other factors that affect the tooth whitening reaction includes pH and the presence of a stabilizing agents. For example, compositions 1D, 1E and 1G all contain the same concentration of hydrogen peroxide. If hydrogen peroxide were simply a result-effective variable each composition would whiten the

same amount. However, since the whitening composition is dependent on many other factors, compositions 1D, 1E and 1G all whiten at different levels. Yet another example of how simply adding more hydrogen peroxide increases the whitening effect is the comparison between Opalescence and compositions 1A, 1B and 1C. Another good example that hydrogen peroxide is not the only factor in the tooth whitening reaction is the comparison in Table 4 between Example 3 and composition 1E. In these two compositions are very similar except for the pH. If optimization of the hydrogen peroxide were the only variable in the tooth whitening reaction, both Example 3 and composition 1E would whiten the same amount. However, that is not the case because composition 1E whitens at a greater rate than Example 3. Thus, that further demonstrates that optimization of hydrogen peroxide is not the only factor which effects teeth whitening and merely optimizing the hydrogen peroxide concentration does not necessarily optimize the whitening.

Therefore, since so many factors affect the tooth whitening reaction in addition to the concentration of hydrogen peroxide, the present application is not merely teaching the optimization of a result effective variable.

Yet another factor to take into consideration is that Williams teaches the use of a bicarbonate salt and that the peroxide is in an acidic environment. (Col. 2, lines 25-27). When a bicarbonate salt and an acid are combined, the resulting chemical reaction has a foaming or effervescent effect because of the release of CO<sub>2</sub>. As a result, Williams teaches a toothpaste that will have a foaming or effervescent effect. The present invention teaches a gel that is not going to have a foaming or effervescent effect based on the disclosed compounds. Furthermore, a foaming or effervescent effect in teeth whitening is disfavored because if hydrogen peroxide is breaking down to quickly causing effervescence, the oxidizing potential of hydrogen peroxide is not being used to whiten teeth.

Claims 57-58, 61, 63, 64, 67-70 are dependent from claim 56. Claims 72-73, 75 and 76 are dependent from claim 71. Claims 80 and 81 from claim 78. These dependent claims are also rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Collin. While Applicant does not acquiesce with the particular rejections to dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 56, 71, and 78. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features which further distinguish these claims

from the cited references. Therefore, dependent claims 57-58, 61, 63, 64, 67-70, 72-3, 75, 76, 80 and 81 are also in condition for allowance.

As discussed in the foregoing, Applicant respectfully submits that Williams in view of Collin does not render the present invention unpatentable. Therefore, Applicant respectfully requests that the rejection of claims 56-57, 61, 63, 64, 70-73, 75, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Collin be withdrawn. Reconsideration is respectfully requested.

**Claims 62, 75 and 79 under 35 U.S.C. § 103 over Williams in view of Collin and further in view of Burke**

Claims 62, 75 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Collin as applied to claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 in further view of Burke et al. (US 5,292,502).

The primary and secondary references, Williams et al. and Collin et al. are discussed above. As discussed in the foregoing, Williams in view of Collin does not render the present invention unpatentable. Furthermore, Applicant respectfully submits that the inclusion of Burke to the combination of Williams and Collin does not supply the deficiencies in order to render the present invention unpatentable.

Applicant respectfully traverses the rejection.

As discussed in the foregoing, simply optimizing the concentration of hydrogen peroxide is not simply optimizing a result effective variable.

Furthermore, as discussed in the foregoing, Williams teaches away from the present invention because of the lower peroxide content disclosed in Williams and that Williams teaches a composition that has a foam or effervescent effect. Applicant believes that Collin does not overcome the deficiencies of Williams. Namely, Collin does not disclose higher peroxide concentrations and Collin also discloses a foaming or effervescent oral care composition.

The Examiner cited Burke for teaching pH-adjusting agents. Applicant points out that Burke does not overcome the deficiencies of Williams. For instance, Burke does not disclose higher peroxide concentrations and Burke also teaches a foaming composition. Burke teaches the use of sodium lauryl sulfoacetate in combination with foam-enhancing non-ionic material to create a composition with enhanced foaming properties. (Cols. 1-2, lines 66-5).

Therefore, Applicant asserts that claims 62, 75 and 79 are patentable. Reconsideration is respectfully requested.

**Claims 56, 57, 61, 62, 65 and 70 under 35 U.S.C. § 103 over Wagner in view of Collin**

Claims 56, 57, 61, 62, 65 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner (US 5,302,374) in view of Collin as applied to claims in view of Collin.

According to the Examiner, Wagner discloses an oral care hygiene system comprising conventional toothpaste along with an abrasive free dentifrice containing hydrogen peroxide. The hydrogen peroxide gel includes 0.2% to 10% hydrogen peroxide, Carbomer 940, humectant, sweetening agents and deionized water. EDTA can also be used. The second paste contains water, tetrasodium pyrophosphate and sodium hydroxide. According to the Examiner, Wagner also discloses that hydrogen peroxide decomposes more rapidly at elevated pH levels.

According to the Examiner, Collin discloses a multiple barrel dispensing device for intermixing two viscous materials.

The Examiner points out that Wagner and the present invention have a slight overlap of hydrogen peroxide concentration at 10%.

The Examiner believes that although Wagner does not disclose any tooth whitening effect, as the compositions are similar, it is reasonable to conclude that Wagner would be capable of a similar tooth bleaching effect.

Applicant respectfully traverses the rejection.

Wagner teaches away from the present invention. Applicant has amended claims 6, 71 and 78 have been amended to include the further limitation that the composition be abrasive free.

Wagner teaches a combining a hydrogen peroxide containing compound with conventional toothpaste. According to the present invention tooth whitening toothpaste are “mechanically agitated at the stained tooth surface in order to affect tooth stain removal through abrasive erosion of stained acquired pellicle.” (Paragraph 5)

On the other hand, the present invention teaches a composition that accomplishes “the tooth-bleaching effect by a chemical process....” (Paragraph 5). As such, the present invention has no need for the inclusion of an abrasive since mechanical agitation is not involved.

Therefore, Williams teaches away from the present invention.

In Example 2 of Wagner, an abrasive is present: hydrated silica. (Col. 3, lines 56-57). Toothpastes contain abrasives to remove various particles from the teeth. Although the hydrogen peroxide containing composition of Wagner is abrasive free, the overall composition when it is combined with the toothpaste of Example 2 will contain abrasives. Therefore, since Wagner teaches an oral care composition that includes abrasives, it teaches away from the present invention that is abrasive free.

According to the Examiner, Wagner and the present invention have a slight overlap with respect to the concentration of peroxide in the composition and that such an overlap is a prima facie case of obviousness. However, according to the Manual of Patent Examining Procedure § 2144.05(III), the Applicant can rebut this prima facie case of obviousness if it can be shown that the prior art teaches away from the present invention.

Wagner uses peroxide mainly in the lower range because high concentrations of peroxide are harmful to the soft tissue of the oral cavity. Wagner discloses a toothpaste so it will come into contact with the soft tissue of the oral cavity as users are brushing their teeth. As such, Wagner will use a lower concentration of peroxide to prevent patient discomfort.

On the other hand, the present invention teaches a higher concentration of peroxide because it will only be applied to the teeth. Unlike brushing teeth where the composition will come into contact with the soft tissue of the oral cavity as a result of the mechanical agitation of the composition by the toothbrush, during a tooth whitening procedure, the composition will not come into contact with the soft tissue of the oral cavity. As a result, higher concentrations of peroxide can be used since soft tissue irritation is no longer an issue and higher concentration of hydrogen peroxide is one factor in many for teeth whitening. Thus, Wagner teaches away from the present invention.

Claims 57, 61, 62, 62 and 70 are dependent from claims 56, and are also rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner in view of Collin. While Applicant does not acquiesce with the particular rejections to dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 56. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 57, 61, 62, 62 and 70 are also in condition for allowance.

As discussed in the foregoing, Applicant respectfully submits that Williams in view of Collin does not render the present invention unpatentable. Therefore, Applicant respectfully requests that the rejection of claims 56-57, 61, 62, 62 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner in view of Collin be withdrawn. Reconsideration is respectfully requested.

### **Obvious Type Double Patenting**

Claims 56-58, 61-65, 67-76 and 78-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-16 of copending application 11/256654 in view of Collin.

According to the Examiner, the conflicting claims are not identical, but not patentably distinct. The claims comprise two part compositions where the first part is a hydrogen peroxide containing component and the second is a pH adjusting agent. The copending claims also mix the two parts prior to use. The claims are different in that the copending claims do not recite a chelating agent or a static mixer in the independent claims. According to the Examiner, Collins supplies the deficiencies and that it would have been obvious to one of ordinary skill in the art use a multichamber vessel to mix the compositions of the copending claims prior to use in a preferred volumetric ratio.

As discussed in the previously filed Amendment, Applicant is willing to file a terminal disclaimer and requests the Examiner hold the requirement of a terminal disclaimer in abeyance until at least one set of claims is found to be allowable. The Examiner has maintained this rejection since Applicant has not responded to the rejection in a substantive manner.

Although Applicant does not agree with all the analysis and conclusions, in the interest of advancing prosecution, Applicant is willing to submit a terminal disclaimer. However, since this is a provisional rejection, Applicant respectfully requests the Examiner to hold the requirement of a terminal disclaimer in abeyance until one of the sets of claims is found to be allowable. Favorable action is respectfully requested.

### **CONCLUSION**

The applicant believes that this Amendment addresses all of the points raised in the Office Action, and requests reconsideration and allowance of the present application.



If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-845-8312.

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Respectfully submitted,

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